Remarks

The Invention

One embodiment of the invention (claims 25-36) provides a method of treating a Chlamydia infection in a patient. The method comprises the steps of administering to the patient a therapeutically effective amount of an immunogenic protein. The immunogenic protein is Chlamydia ribosomal protein L7/L12, a homologue of Chlamydia ribosomal protein L7/L12, or a fragment of ribosomal protein L7/L12.

Another embodiment of the invention (claims 37-48) provides a method of preventing a Chlamydia infection in a patient. The method comprises the steps of administering to the patient a prophylactically effective amount of an immunogenic protein. The immunogenic protein is Chlamydia ribosomal protein L7/L12, a homologue of Chlamydia ribosomal protein L7/L12, or a fragment of ribosomal protein L7/L12.

Claim Amendments

Claims 25 and 37 are amended to recite "Chlamydia" ribosomal protein L7/L12 and a homolog of "Chlamydia" ribosomal protein L7/L12. Claims 26 and 38 are amended to recite "Chlamydia ribosomal protein L7/L12." Claims 27, 35, 39, and 47 are amended to recite "a MW of about 15.8 kDa and a pI of about 4.8" thus removing reference to a MW and pI characteristics of protein 12 set out in Table II of page 15. Claims 28 and 40 are amended to recite a protein with "an N-terminal amino acid sequence of TTLESLETLVE (SEQ ID NO:2)" thus removing reference to an amino acid sequence set out on page 16. Claims 31 and 43 are amended to recite a fragment that comprises at least 7 consecutive amino acids of "ribosomal protein L7/L12." The claims

were amended to more clearly describe the invention. The claims have not been narrowed in scope. No new matter is added by these claim amendments.

Amendment to the Specification

The specification is amended to add the phrase "We claim" before the claims, thus correcting an informality noted in the Office Action. The specification was also amended to correct a typographical error to the paragraph on page 2, lines 7-10. Protein 12 was inadvertently omitted from the paragraph. Support for inclusion of protein 12 can be found *inter alia* in Table II. In addition, a replacement FIG. 1 is provided. The numbers and reference characters are legible. No new matter is added by these amendments.

The Rejection of Claims 25-48 Under 35 U.S.C. § 112, First Paragraph

Claims 25-48 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to provide an adequate written description and enablement. In particular the rejection asserts that the application fails to disclose that ribosomal L7/L12 protein has been shown to treat or prevent a Chlamydia infection. In addition, the rejection asserts that the application fails to adequately describe homologues of ribosomal L7/L12 protein or fragments of ribosomal L7/L12 protein with at least 7 amino acids. Applicants respectfully traverse this rejection

An analysis of whether a claim is enabled by the specification requires a determination of whether the specification contains sufficient information, together with knowledge in the prior art, to enable one skilled in the art to make and use the claimed

invention without undue experimentation. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 837 F.2d 778, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988).

An application as filed is presumed to have an adequate written description. *In re Marzacchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971). The specification need only describe in detail that which is new or not conventional. *Hybritech v. Monoclonal Antibodies*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). The U.S. Patent and Trademark Office has the initial burden of presenting by a preponderance of evidence why a skilled artisan would not recognize a description in an application as adequate for describing the claimed invention. *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (CCPA 1976).

Independent claim 25 and dependent claims 26-36 are directed to a method of treating a Chlamydia infection in a patient. Independent claim 37 and dependent claims 38-48 are directed to a method of preventing a Chlamydia infection in a patient. The methods comprise the step of administering to the patient a therapeutically or prophylactically (respectively) amount of an immunogenic protein. The immunogenic protein is (1) a Chlamydia ribosomal protein L7/L12, (2) a homologue of the Chlamydia ribosomal protein L7/L12, or (3) a fragment of ribosomal protein L7/L12.

The Office Action asserts that the ribosomal protein L7/L12 protein has not been shown to treat or prevent a Chlamydia infection, or that homologues or fragments of ribosomal protein L7/L12 have been described. Office Action at page 3. However, the Office Action has failed to provide any reasoning as to why a skilled artisan would find

the disclosure to lack a written description and to be enabled. Thus, the Office Action has failed to establish a *prima facie* case of lack of written description and enablement.

In contrast, applicants have provided an adequate written description such that a skilled artisan would find the claimed invention to be adequately described. First, applicants teach that Chlamydia ribosomal protein L7/L12 is an immunogenic protein. "Seven patients showed reactivity to this [ribosomal protein L7/L12] protein, demonstrating that it is immunogenic in humans as a consequence of chlamydial infection." Page 12, lines 10-12. Second, the applicant reports actual usage and teaches that forty-one percent of patient immune sera tested were positive for chlamydial ribosomal protein L7/L12. "Patient immune reactions were also detected against the following proteins: . . . spot 12 – ribosomal protein L7/L12 (7/17)." Page 8, lines 19-22. Third, applicants teach that newly identified Chlamydia immunogens, like the chlamydial ribosomal L7/L12 protein, belong to conserved families of bacterial proteins. "[I]t is noteworthy that several of these new immunoreactive antigens belong to conserved families of bacterial proteins: . . . seven sera (41%) recongised [*sic*] spot 12 (the ribosomal protein L7/L12)." Page 12, line 27 to page 13, line 1.

The skilled artisan would find adequate written description and enablement for treating or preventing a Chlamydia infection by administering a Chlamydia ribosomal L7/L12 protein, a homologue of chlamydial ribosomal protein L7/L12, or a fragment of ribosomal protein L7/L12. Withdrawal of this rejection is respectfully requested.

The Rejection of Claims 25-48 Under 35 U.S.C. § 112, Second Paragraph

Claims 25-48 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for recitation of "ribosomal protein L7/L12," "the protein has MW and pI characteristics of protein 12," amino acid sequence disclosed in Table III on page 16," and "at least 7 consecutive amino acids."

As discussed above, claims 36 and 48 are canceled. Claims 25 and 37 are amended to recite "Chlamydia" ribosomal protein L7/L12 and a homolog of "Chlamydia" ribosomal protein L7/L12. Claims 26 and 38 are amended to recite a homolog of "Chlamydia ribosomal protein L7/L12." Claims 27, 35, 39, and 47 are amended to recite "a MW of about 15.8 kDa and a pI of about 4.8" thus removing reference to a MW and pI characteristics of protein 12 set out in Table II of page 15. Claims 28 and 40 are amended to recite a protein with "an N-terminal amino acid sequence of TTLESLETLVE (SEQ ID NO:2)" thus removing reference to an amino acid sequence set out on page 16. Claims 31 and 43 are amended to recite a fragment that comprises at least 7 consecutive amino acids of "ribosomal protein L7/L12." Withdrawal of this rejection is respectfully requested.

An Information Disclosure Statement is attached which lists three references relating to *Brucella*. The Oliveira reference was identified within the last month. It relates to subject matter already discussed in the specification at page 12, lines 13-14. In order to complete the record copies of references 27 and 28 identified in the specification at page 12 are also enclosed. In addition, the references in the International Search Report are listed in the Information Disclosure Statement.

Respectfully submitted,

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